HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

D1276B

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
P.O. Box 3012
Bothell, WA 98041-3012

Telephone: 206-486-8788
FAX: 206-483-4996

March 20, 1997

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 97-12

WARNING LETTER

Leo R. McDonnell, Owner
Midland Bull Test Ranch
RR 1 Box 304C
Columbus, Montana 59019

Dear Mr. McDonnell:

An investigation at your bull testing operation located at Columbus, Montana, conducted on March 3-4, 1997, confirmed that you offered an animal for sale for food in violation of Sections 402(a)(2)(D) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), and that you caused an animal drug to become adulterated within the meaning of Section 501(a)(5).

On January 8, 1997, you sold a bull, identified with ear tag number 657, for slaughter as human food to [redacted] USDA analysis of tissue samples collected from this bull identified the presence of 17.0 ppm and 13.0 ppm of sulfamethazine in the liver and muscle, respectively. A tolerance of 0.1 ppm has been established for residues of sulfamethazine in the edible tissues of cattle, Title 21, Code of Federal Regulations, Part 556.670. The presence of this drug in edible tissues from this bull causes the food to be adulterated within the meaning of Section 402(a)(2)(D) of the Act.

Our investigation also found that you hold animals under conditions which allow medicated animals bearing potentially harmful drug residues to enter the food supply. For example, you lack an adequate system for: a) recording who administers a drug, date of medication, the drug used, dosage administered, and the pre-slaughter withdrawal time; b) assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Foods from animals held under such conditions are adulterated within the meaning of section 402(a)(4) of the Act.

You are adulterating the drug [redacted] brand of sulfamethazine

your ranch uses on bulls within the meaning of Section 501(a)(5) when you fail to use the drug in conformance with its approved labeling. Your use of the drug, without following the labeled withdrawal period, causes the drug to be unsafe to use.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 working days of the steps you have taken to bring your ranch into compliance with the law. Your response should include each step being taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Richard S. Andros, Compliance Officer, at the above address.

Sincerely yours,

Roger L. Lowell
District Director